

CHAPTER 39
REGISTRATION OF RADIATION MACHINE FACILITIES, LICENSURE OF RADIOACTIVE
MATERIALS AND TRANSPORTATION OF RADIOACTIVE MATERIALS

641—39.1(136C) Purpose and scope.

39.1(1) All persons possessing radiation machines within the state shall be registered in accordance with this chapter, except as specifically exempted.

39.1(2) No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a specific or general license issued pursuant to this chapter or as otherwise provided in these rules.

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1998.

39.1(4) In addition to the requirements of this chapter, all registrants are subject to the requirements of 641—Chapters 38 and 40. Furthermore, registrants engaged in healing arts are subject to the requirements of 641—Chapters 41 and 42; registrants engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45.

641—39.2(136C) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 38 may also apply to this chapter.

641—39.3(136C) Requirements for registration of X-ray and other electronic machines that produce radiation.

39.3(1) Exemptions.

a. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this chapter, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 μ Sv) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

b. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this chapter.

c. Domestic television receivers are exempt from the requirements of this chapter.

39.3(2) Application for registration of radiation machine facilities. Each person having a radiation machine facility shall:

a. Apply for registration of such facility with the agency prior to the operation of a radiation machine facility. In order to register equipment, the person must have a permanent office located in Iowa that has a telephone, employee and equipment, and storage for records regarding the equipment and operator certification. Application for registration shall be completed on forms furnished by the agency and shall include the appropriate fee from 641—38.8(136C).

b. Designate on the application form an individual to be responsible for radiation protection.

c. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 39.3(3)“d” to the registrant’s radiation machine facility until such person provides evidence that the person has been registered with the agency as a provider of services in accordance with 39.3(3).

39.3(3) *Application for registration of servicing and services.*

a. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state shall apply for registration of such services with the agency prior to furnishing or offering to furnish any such services.

b. Application for registration shall be completed on forms furnished by the agency and shall contain all information required by the agency as indicated on the forms and accompanying instructions and include the fee required in 641—paragraph 38.8(1)“c.”

c. Each person applying for registration under this chapter shall specify:

(1) That the person has read and understands the requirements of these rules;

(2) The services for which the person is applying for registration;

(3) The training and experience that qualify the person to discharge the services for which the person is applying for registration;

(4) The type of measurement instrument to be used, frequency of calibration, and source of calibration; and

(5) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

d. For the purpose of 39.3(3), services may include but shall not be limited to:

(1) Installation and servicing of radiation machines and associated radiation machine components;

(2) Calibration of radiation machines or radiation measurement instruments or devices;

(3) Radiation protection or health physics consultations or surveys; and

(4) Personnel dosimetry services.

e. No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the agency.

39.3(4) *Issuance of notice of registration.*

a. Upon a determination that an applicant meets the requirements of this chapter, the agency shall issue a notice of registration.

b. The agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

39.3(5) *Expiration of notice of registration.* Except as provided by 39.3(6) "b," each notice of registration shall expire within 12 months of issuance or at the end of the specified day in the month and year stated therein.

39.3(6) *Renewal of notice of registration.*

a. Application for renewal of registration shall be filed in accordance with 39.3(2) or 39.3(3).

b. In any case in which a registrant has properly filed an application for renewal of current registration within 90 days prior to the expiration of the existing registration, such existing registration shall not expire until the application status has been finally determined by the agency.

39.3(7) *Report of changes.* The registrant shall notify the agency in writing before making any change which would render the information contained in the application for registration or the notice of registration no longer accurate.

39.3(8) *Approval not implied.* No person, in any advertisement, shall refer to the fact that the person or the person's facility is registered with the agency pursuant to the provisions of 39.3(2) or 39.3(3), and no person shall state or imply that any activity under such registration has been approved by the agency.

39.3(9) *Assembler and transfer obligation.*

a. Any person who sells, leases, transfers, lends, disposes of, assembles, or installs radiation machines in this state shall notify the agency in writing within 15 days of:

- (1) The name and address of persons who have received these machines;
- (2) The manufacturer, model, and serial number of each radiation machine transferred; and
- (3) The date of transfer of each radiation machine.

b. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation and used, shall meet the requirements of 641—Chapters 38, 39, 40 and 41.

c. In the case of diagnostic X-ray systems which contain certified components, a copy of the assembler's report prepared in accordance with the requirements of the federal diagnostic X-ray standard (21 CFR 1020.30(d)) shall be submitted to the agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

39.3(10) *Reciprocity—out-of-state radiation machines.*

a. Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the agency at least two working days before such machine is to be used in the state. The notice shall include:

- (1) The type of radiation machine;
- (2) The nature, duration, and scope of use;
- (3) The exact location(s) where the radiation machine is to be used; and
- (4) States in which this machine is registered.

b. If, for a specific case, the two-working-day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.

c. The person referred to in 39.3(10)“a” shall:

- (1) Comply with all applicable rules of the agency;
- (2) Supply the agency with such other information as the agency may reasonably request; and
- (3) Not operate within the state on a temporary basis in excess of 180 calendar days in a 365-day reciprocity period. The 365-day reciprocity period starts on the day the agency receives the appropriate fee, as specified in 641—subrule 38.8(8), and ends exactly 365 days later. It is the registrant’s responsibility to ensure the 180-day limit is not exceeded during the 365-day reciprocity period and to ensure that the reciprocal recognition is renewed 30 days prior to the expiration of the 365-day reciprocity period.

39.3(11) Exemption. Rescinded IAB 4/8/98, effective 7/1/98.

641—39.4(136C) Requirements for licensing of radioactive materials.

39.4(1) *In addition to the requirements of this chapter, all licensees are subject to the requirements of 641—Chapters 38, 40 and 41. Furthermore, licensees engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45; licensees using radionuclides in the healing arts are subject to the requirements of 641—41.2(136C) and 641—Chapter 42; and licensees engaged in land disposal of radioactive material are subject to the requirements of 641—Chapter 40.*

39.4(2) Source material.

a. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

b. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

c. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers:

- (1) Any quantities of thorium contained in:
 1. Incandescent gas mantles,
 2. Vacuum tubes,
 3. Welding rods,
 4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium,
 5. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium,

6. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

7. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.

(2) Source material contained in the following products:

1. Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

2. Glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,

3. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or

4. Piezoelectric ceramic containing not more than 2 percent by weight source material.

(3) Photographic film, negatives, and prints containing uranium or thorium.

(4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

1. The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40,

2. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM,"

3. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED," and

4. This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(6) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

1. The shipping container is conspicuously and legibly impressed with the legend "CAUTION—RADIOACTIVE SHIELDING—URANIUM," and

2. The uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

1. The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

2. The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(8) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium.

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

1. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and